SEP 2 3 2003

K032242

EXHIBIT 2

OMI Manufacturing Pty Ltd
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Queensland 4127
Australia
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Contact: Mr. Bruce L. Kiehne, Director/Secretary

510(k) Summary

1. Identification of the Device:
   Proprietary-Trade Name: PersonnaPlus Safety Scalpel System also known as OMI Safe Scalpel
   Classification Name: Blade: GES, Handle: GDZ
   Common/Usual Name: Scalpel blade, scalpel handle
   This device is Class I but with sharps injury protection feature.

2. Equivalent legally marketed device: K923170 Los Alamos Retractable Knife and Personna Safety Scalpel" K924503

3. Indications for Use (intended use) The PersonnaPlus Safety Scalpel System is a surgical safety scalpel intended for use as a cutting device during surgical, pathology and minor medical procedures. It is intended to aid in the protection against accidental injuries during loading, passing, and disposal..

4. Description of the Device: The device is a combination scalpel blade and handle incorporating a sharps injury protection feature. There are two product options –
   (1) a totally disposable unit and
   (2) a metal handle with disposable blade and guard - our "reposable" product. The totally disposable unit uses a plastic handle while the reposable product has a stainless steel handle.

5. Safety and Effectiveness, comparison to predicate device:

Device Characteristics	K923170 Los Alamos Retractable Knife	PersonnaPlus Medical Safety Scalpel and Blades
Indications for use	General surgical use	SAME
Safety feature	Retractable blade	Blade guard retracts
Single use or reusable	Single use only, disposable.	Reusable with change of blade and re-sterilization of handle
Blade size(s)	10, 11, 15	Handle sizes 3, 4 Blade sizes: 10,11,15,15C, 20, 21, 22, 23, 24
Blade material	Stainless steel	SAME
Handle material	Plastic	Plastic or Stainless steel
Supplied	Sterile	SAME

6. In all respects, the PersonnaPlus Safety Scalpel System also known as OMI Safe Scalpel are substantially equivalent to one or more scalpels currently marketed in the USA. The scalpels are constructed of identical materials and conform to applicable ISO standards. An added safety feature of a retractable plastic shroud around the blade enhances safety. A successful simulated user study was conducted according to FDA guidance document Supplementary Guidance on Premarket Notifications for Medical Devices with Sharps Injury Prevention Features; Guidance for Industry and FDA Document Issued on: December 31, 2002

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 3 2003

Omi Manufacturing Pty, Limited
C/O Mr. George Kreimer
Responsible Third Party Official
Underwriters Laboratories, Incorporated
333 Pfingsten Road
Northbrook, Illinois 60062

Re: K032242
Trade/Device Name: Personna Plus Safety Scalpel System
Regulation Number: 878.4800
Regulation Name: Manual Surgical Instrument for General Use
Regulatory Class: I
Product Code: GES, GDZ
Dated: September 4, 2003
Received: September 5, 2003

Dear Mr. Kreimer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

k) Indications for Use

510(k) Number_____

Device Name: PersonnaPlus Safety Scalpel System also known as OMI Safe Scalpel..

Indications for Use: The PersonnaPlus Safety Scalpel System is a surgical safety scalpel intended for use as a cutting device during surgical, pathology and minor medical procedures. It is intended to aid in the protection against accidental injuries during loading, passing, and disposal.

_____ _____ _____ _____ _____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over the Counter Use_____
(Per 21 CFR 801.109)

Patricia Cucuzzella

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K032242